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LIGATING CLIP WITH INTEGRAL TISSUE-SECURING MECHANISM

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Description

LIGATING CLIP WITH INTEGRAL TISSUE-SECURING MECHANISM

Technical Field

The present invention relates to surgical clips, and more particularly to ligating clips with an integral tissue-securing mechanism to impede the longitudinal movement of the ligating clip along a vessel engaged by the clip. Yet more particularly, the present invention relates to an improved surgical ligating clip that is provided with an interlocking mechanism integral to the legs of the clip that serve to secure the tissue or vessel engaged by the clip.

Background Art

Many surgical procedures require vessels or other tissues of the human body to be ligated during the surgical process. For example, many surgical procedures require cutting blood vessels (e.g., veins or arteries), and these blood vessels may require ligation to reduce bleeding. In some instances, a surgeon may wish to ligate the vessel temporarily to reduce blood flow to the surgical site during the surgical procedure. In other instances a surgeon may wish to permanently ligate a vessel. Ligation of vessels or other tissues can be performed by closing the vessel with a ligating clip, or by suturing the vessel with surgical thread. The use of surgical thread for ligation requires complex

manipulations of the needle and suture material to form the knots required to secure the vessel. Such complex manipulations are time-consuming and difficult to perform, particularly in endoscopic surgical procedures, which are characterized by limited space and visibility. By contrast, ligating clips are relatively easy and quick to apply. Accordingly, the use of ligating clips in endoscopic as well as open surgical procedures has grown dramatically.

Various types of hemostatic and aneurysm clips are used in surgery for ligating blood vessels or other tissues to stop the flow of blood. Such clips have also been used for interrupting or occluding ducts and vessels in particular surgeries such as sterilization procedures. Typically, a clip is applied to the vessel or other tissue by using a dedicated mechanical instrument commonly referred to as a surgical clip applier, ligating clip applier, or hemostatic clip applier. Generally, the clip is left in place after application to the tissue until hemostasis or occlusion occurs. At some point thereafter, the clip is removed by using a separate instrument dedicated for that purpose, i.e., a clip removal instrument.

Ligating clips can be classified according to their geometric configuration (e.g., symmetric clips or asymmetric clips), and according to the material from which they are manufactured (e.g., metal clips or polymeric clips). Symmetric clips are generally "U" or "V" shaped and thus are substantially symmetrical about a central, longitudinal axis extending between the legs of the clip. Symmetric clips are usually constructed from metals such as stainless steel, titanium, tantalum, or alloys thereof. By means of a dedicated clip applier, the metal clip is permanently deformed over the vessel. An example of one such

clip is disclosed in U.S. Patent No. 5,509,920 to Phillips et al. An example of a metallic clip applier is disclosed in U.S. Patent No. 3,326,216 to Wood in which a forceps-type applier having conformal jaws is used to grip and maintain alignment of the clip during deformation. Such appliers may additionally dispense a plurality of clips for sequential application, as disclosed in U.S. Patent No. 4,509,518 to McGarry et al.

With the advent of high technology diagnostic techniques using computer tomography (CATSCAN) and magnetic resonance imaging (MRI), metallic clips have been found to interfere with the imaging techniques. To overcome such interference limitations, biocompatible polymers have been increasingly used for surgical clips. Unlike metallic clips, which are usually symmetric, polymeric clips are usually asymmetric in design and hence lack an axis of symmetry. Inasmuch as the plastic clip cannot be permanently deformed for secure closure around a vessel or other tissue, latching mechanisms have been incorporated into the clip design to establish closure conditions and to secure against re-opening of the vessel. For example, well known polymeric clips are disclosed in U.S. Patent No. 4,834,096 to Oh et al. and U.S. Patent No. 5,062,846 to Oh et al., both of which are assigned to the assignee of the present invention. These plastic clips generally comprise a pair of curved legs joined at their proximal ends with an integral hinge or heel. The distal ends of the curved legs include interlocking latching members. For example, the distal end of one leg terminates in a lip or hook structure into which the distal end of the other leg securely fits to lock the clip in place.

The distal ends of the clips taught by Oh et al. also include lateral bosses that are engaged by the jaws of the clip applier. A clip applier specifically designed for asymmetric plastic clips is used to close the clip around the tissue to be ligated, and to latch or lock the clip in the closed condition. In operation, the jaws of this clip applier are actuated into compressing contact with the legs of the clip. This causes the legs to pivot inwardly about the hinge, thereby deflecting the hook of the one leg to allow reception therein of the distal end of the other leg. A clip applier designed for use with asymmetric plastic clips in an open (i.e., non-endoscopic) surgical procedure is disclosed in U.S. Patent No. 5,100,416 to Oh et al., also assigned to the assignee of the present invention.

In addition to compatibility with sophisticated diagnostic techniques, asymmetric clips have other advantages over symmetric clips. For example, because asymmetric clips are formed from polymeric materials, the mouths of asymmetric clips can be opened wider than the mouths of symmetric clips. This allows a surgeon to position the clip about the desired vessel with greater accuracy. In addition, a clip of the type described in U.S. Patent Nos. 4,834,096 and 5,062,846 to Oh et al. can be repositioned before locking the clip on the vessel or before removing the clip from the vessel, in a process referred to as "approximating" the clip.

Although plastic ligating clips are well known in the surgical area and improvements have been made to the ligating clips, including providing protrusions on the inner surfaces of the leg members to impede the lateral movement of a vessel during clip closure (see, for example, the

aforementioned U.S. Patent Nos. 4,834,096 and 5,062,846), these improvements have been less effective in preventing longitudinal movement of a vessel or tissue during and after clip closure. Accordingly, there is a need to provide an improved polymeric surgical ligating clip with an interlocking mechanism integral to the legs of the clip that serves to secure the tissue or vessel engaged by the clip.

Summary of the Invention

In accordance with the present invention, a polymeric surgical clip is provided of the type comprising first and second leg members joined at their proximal ends by a resilient hinge means. Each leg member has a vessel clamping inner surface and an opposite outer surface, and the vessel clamping inner surface is in opposition to the vessel clamping inner surface of the other leg member. The first leg member terminates at its distal end in a deflectable hook member curved toward the second leg member, and the second leg member terminates at its distal end in a locking portion complimentary to the hook member such that when the first and second leg members are moved from an open position to a closed position about the hinge means, the hook member deflects about the distal end of the second leg member to lock the clip in a closed position. The hook member has a continuously curved outer surface extending distally from the outer surface of the first leg member, side surfaces and an inner surface.

The improvement to the polymeric surgical clip comprises providing an interlock mechanism comprising complimentary parts formed along a portion of

the vessel clamping inner surface of each of the first and second leg members. The complementary parts cooperatively engage when the clip is in the closed position to capture a vessel or other tissue and impede longitudinal movement of the clip in relation to the vessel or other tissue.

The surgical clip of the present invention is preferably made of polymeric material and accordingly minimizes interference with high technology diagnostic modalities such as CAT SCAN, MRI and MRS. At the same time, the clip is nearly as small as comparable metal clips while maintaining sufficient strength and possessing high security in the clip's latching mechanism in the closed position clamping the vessel. The surgical clip is configured to provide a secure means of handling an application to avoid premature release from the applier of the clip.

It is therefore an object of the present invention to provide a polymeric surgical clip capable of occluding a vessel while resisting longitudinal movement along the vessel.

It is another object of the present invention to provide a surgical clip with an interlocking tissue-securing mechanism integral to the inner surfaces of the legs of the clip that serves to secure the clip to the vessel and prevent longitudinal movement of the clip relative to the vessel when the clip is in the closed position.

Some of the objects of the invention having been stated hereinabove, other objects will become evident as the description proceeds when taken in connection with the accompanying drawings as best described hereinbelow.

Brief Description of the Drawings

Figure 1 is an enlarged perspective view of the surgical ligating clip of the present invention;

Figure 2 is an enlarged side elevation view of the surgical ligating clip of the present invention;

Figure 3 is an enlarged, partially sectioned view of the surgical ligating clip viewed along line 3—3 in Figure 2;

Figure 4 shows the clip of Figure 1 applied to a body vessel;

Figure 5 is a cross-sectional view of the clip applied to a body vessel viewed along line 5—5 in Figure 4;

Figure 6 is an enlarged perspective view of an alternate embodiment of the surgical ligating clip of the present invention;

Figure 7 is an enlarged side elevation view of the alternate embodiment of the surgical ligating clip of the present invention;

Figure 8 is an enlarged, partially sectioned view of the alternate embodiment of the surgical ligating clip viewed along line 8—8 in Figure 7;

Figure 9 shows the clip of Figure 6 applied to a body vessel; and

Figure 10 is a cross-sectional view of the clip applied to a body vessel viewed along line 10—10 in Figure 9.

Detailed Description of the Invention

Referring to Figure 1 through Figure 3, an example is illustrated of an asymmetric surgical clip generally designated **100** that is suitable for use in conjunction with the present invention. Clip **100** and others of similar design

are particularly useful as hemostatic clips that can be latched around a vessel or other type of tissue to ligate the vessel and thereby stop or reduce the flow of fluid through the vessel. Clip **100** can be constructed from any suitable biocompatible material, such as certain metals and polymers. However, the present invention is particularly suitable for practice with polymeric clips. Thus, clip **100** preferably comprises a one-piece integral polymeric body formed from a suitable strong biocompatible engineering plastic such as the type commonly used for surgical implants. Examples include polyethylene terephthalate (PET), polybutylene terephthalate (PBT), polyoxymethylene, or other thermoplastic materials having similar properties that can be injection-molded, extruded or otherwise processed into like articles.

Figure 1 is an enlarged perspective view of the surgical ligating clip of the present invention. The body of clip **100** includes a first or outer leg, generally designated **102**, and a second or inner leg, generally designated **104**. First and second legs **102** and **104** are joined at their proximal ends by an integral hinge section, generally designated **106**. First and second legs **102** and **104** have complementary arcuate profiles. Thus, first leg **102** has a concave inner surface **108** and a convex outer surface **110**, and second leg **104** has a convex inner surface **112** and a concave outer surface **114**. Convex inner surface **112** of second leg **104** and concave inner surface **108** of first leg **102** have substantially matching radii of curvature.

Hinge section **106** has a continuous concave inner surface **116** and a continuous convex outer surface **118**. Concave inner surface **116** of hinge section **106** joins concave inner surface **108** of first leg **102** and convex inner

surface **112** of second leg **104**. Convex outer surface **118** of hinge section **106** joins convex outer surface **110** of first leg **102** and concave outer surface **114** of second leg **104**. Curved slot **120** is located between curved hinge surfaces **116** and **118**, and is positioned closer to inner surface **116** than to outer surface **118**. Slot **120** extends completely through hinge section **106** from side to side and its opposite ends **122**, **124** extend into the proximal ends of first and second legs **102** and **104**, respectively. Slot **120** provides added flexibility to hinge section **106**, but the inner concave surface **116** prevents any portion of the clamped vessel from being trapped within slot **120**.

First leg **102** transitions to a curved, C-shaped hook section **126** at its distal end. Second leg **104** transitions to a pointed tip section **128** at its distal end. The distal portion of hook section **126** curves inwardly and points generally toward inner surface **116** of hinge **106**. The hook section has a transverse beveled surface **130** and a concave inner surface **108** that defines a latching recess **132**. The latching recess **132** is adapted for conformally engaging tip section **128** in the course of compressing clip **100** into a latched or locked position around a vessel or other tissue.

In accordance with the invention, raised lip or tongue **134** protrudes from inner surface **112** of second leg **104**. Tongue **134** is oriented longitudinally along a portion of inner surface **112** of second leg **104**. As shown in Figure 2, which is an enlarged side elevation view of the surgical ligating clip of the present invention, the proximal and distal ends of tongue **134** may be curved, giving tongue **134** a generally oval or elliptical profile. Recessed pocket or

groove **136** is formed longitudinally along a portion of inner surface **108** of first leg **102**. Groove **136** has a profile complementary to tongue **134** and is positioned opposite to tongue **134**. Tongue **134** and groove **136** form complementary parts of an interlocking mechanism. Accordingly, when clip **100** is compressed into a latched or locked position, tongue **134** fits within groove **136**. The curved ends of tongue **134** reduce the likelihood that tissue captured in clip **100** will be damaged by tongue **134**. One would appreciate that groove **136** should be larger than tongue **134** to accommodate tongue **134** and the portion of any vessel or tissue captured by clip **100** along tongue **134**.

As best shown in Figure 3, which is a view directed into the open concave side of clip **100** viewed along line 3—3 in Figure 2, clip **100** has parallel, opposed side surfaces. Tongue **134** is approximately centered between side surfaces **138** and **140** of second leg member **104**. Similarly, groove **136** is approximately centered between side surfaces **142** and **144** of first leg member **102**. By centering groove **136** between side surfaces **142** and **144**, approximately equal amounts of clip material are on each of the lateral sides of groove **136** and help secure the captured tissue. The width and length of tongue **134** are smaller than the width and length of groove **136**. As noted above, the larger dimensions of groove **136** permit an amount of tissue to be pushed into groove **136** by tongue **134**. The larger dimensions of groove **136** also aid in the alignment of tongue **134** and groove **136** while clip **100** is being compressed by permitting a certain amount of play in the alignment of first leg **102** and second leg **104**.

Adjacent to the distal end of the first leg **102** and immediately inward of hook section **126**, cylindrical bosses **146** and **148** protrude perpendicular to each of the opposed side surfaces **142** and **144**. In the illustrated example of clip **100**, a bridge section **150** couples bosses **146** and **148** together. As evident in Figure 2, bosses **146** and **148** project outwardly beyond convex outer surface **110** of first leg **102**. At the distal end of second or inner leg **104**, cylindrical bosses **152** and **154** protrude perpendicular to each of the opposed side surfaces **138** and **140** of inner leg **104** at tip section **128**. Bosses **152** and **154** of second leg **104** extend longitudinally forwardly beyond tip section **128**.

In the practice of ligating a vessel as understood by persons skilled in the art, clip **100** is designed to be compressed into a latched or locked position around the vessel through the use of an appropriate clip applicator instrument, such as the type described in the aforementioned U.S. Patent No. 5,100,416. The clip applicator instrument engages bosses **146**, **148**, **152** and **154** of clip **100** and pivots bosses **146**, **148**, **152** and **154** inwardly about hinge section **106**. This causes first and second legs **102** and **104** to close around the vessel, with convex inner surface **112** of second leg **104** and complementary concave inner surface **108** of first leg **102** contacting the outer wall of the vessel. Tongue **134** pushes a portion of the vessel into groove **136**. Tongue **134** and groove **136** effectively secure the clip to the vessel and prevent longitudinal movement of the clip or vessel during or after clip closure. Tip section **128** of second leg **104** then begins to contact hook section **126**. Further pivotal movement by the applicator instrument longitudinally elongates first leg **102** and deflects hook section **126**, allowing tip section **128** to align with

latching recess **132**. Upon release of the applicator instrument, tip section **128** snaps into and is conformably seated in latching recess **132**, at which point clip **100** is in its latched condition and the vessel securely engaged thereby.

Figure 4 is an enlarged, perspective view of clip **100** compressed around a portion of a vessel. In the latched condition, tip section **128** is engaged between concave inner surface **108** and beveled surface **130**, thereby securely clamping a designated vessel or other tissue between concave inner surface **108** and convex inner surface **112**.

Figure 5 is a cross sectional view of clip **100** engaged around a portion of a vessel as viewed along line 5—5 in Figure 4. In the area where clip **100** is applied to the vessel, tongue **134** makes contact with a portion of the vessel and pushes the vessel into groove **136**. The portion of the vessel in contact with tongue **134** conforms around tongue **134** as the vessel is pushed into groove **136**. Longitudinal movement of the vessel relative to clip **100** is resisted primarily by the portion of the vessel trapped between the sides of tongue **134** and the sides of groove **136**.

Figures 6-10 depict an alternate embodiment of an asymmetric surgical clip **200** in accordance with the invention. Clip **200** bears many similarities to clip **100** described above with reference to Figures 1-5. For example, the materials and procedures used to make and apply clip **100** may be used to make and apply clip **200** as well. Similarly, the various features of clip **100** described above are referenced where appropriate in Figures 6-10 with respect to clip **200** using the same reference numerals used in Figures 1-5.

Figure 6 is an enlarged perspective view of clip **200**. The body of clip **200** includes a first or outer leg, generally designated **102**, and a second or inner leg, generally designated **104**. First and second legs **102** and **104** are joined at their proximal ends by an integral hinge section, generally designated **106**. First and second legs **102** and **104** have complementary arcuate profiles. Thus, first leg **102** has a concave inner surface **108** and a convex outer surface **110**, and second leg **104** has a convex inner surface **112** and a concave outer surface **114**. Convex inner surface **112** of second leg **104** and concave inner surface **108** of first leg **102** have substantially matching radii of curvature.

Hinge section **106** has a continuous concave inner surface **116** and a continuous convex outer surface **118**. Concave inner surface **116** of hinge section **106** joins concave inner surface **108** of first leg **102** and convex inner surface **112** of second leg **104**. Convex outer surface **118** of hinge section **106** joins convex outer surface **110** of first leg **102** and concave outer surface **114** of second leg **104**. Curved slot **120** is located between curved hinge surfaces **116** and **118**, and is positioned closer to inner surface **116** than to outer surface **118**. Slot **120** extends completely through hinge section **106** from side to side and its opposite ends **122**, **124** extend into the proximal ends of first and second legs **102** and **104**, respectively.

First leg **102** transitions to a curved, C-shaped hook section **126** at its distal end. Second leg **104** transitions to a pointed tip section **128** at its distal end. The distal portion of hook section **126** curves inwardly and points generally toward inner surface **116** of hinge **106**. The hook section has a

transverse beveled surface **130** and a concave inner surface **108** that defines a latching recess **132**. The latching recess **132** is adapted to conformally engage tip section **128** in the course of compressing clip **100** into a latched or locked position around a vessel or other tissue.

In accordance with the alternate embodiment of the invention, complementary parts of an interlocking mechanism are formed along the inner surfaces of first leg **102** and second leg **104**. In this embodiment, the complementary parts are arranged in a lock-step configuration. A raised lip or tongue **202** protrudes from and is oriented longitudinally along a portion of inner surface **112** of second leg **104**. Recessed pocket or groove **204** is formed adjacent to tongue **202** and runs parallel to tongue **202** along inner surface **112** of second leg **104**. Another tongue **202** and groove **204** are similarly arranged along inner surface **108** of first leg **102**, with tongue **202** of one leg member aligned opposite to groove **204** of the other leg member so as to interlock when clip **100** is closed.

As shown in Figure 7, which is an enlarged side elevation view of the surgical ligating clip of the present invention, the proximal and distal ends of tongue **202** may be curved, giving tongue **202** a generally oval or elliptical profile. Groove **204** has a profile complementary to tongue **202** and is positioned opposite to tongue **202**. Each tongue **202** and groove **204** pair form complementary parts of an interlocking mechanism. Accordingly, when clip **200** is compressed into a latched or locked position, each tongue **202** fits within the opposing groove **204**. The curved ends of tongue **202** reduce the likelihood that tissue captured in clip **200** would be damaged by tongue **202**. One would

appreciate that groove **204** should be larger than tongue **202** to accommodate tongue **202** and the portion of any vessel or tissue captured by clip **200** along tongue **202**.

As best shown in Figure 8, which is a view directed into the open concave side of clip **200** viewed along line 8—8 in Figure 7, clip **200** has parallel, opposed side surfaces. Tongue **202** may abut one of the side surfaces of a leg and groove **204** may abut the other side surface of the leg. The portion of the side surface co-incident with groove **204** may follow the profile of groove **204**, thereby providing an open side for groove **204**. The width and length of tongue **202** are smaller than the width and length of groove **204**. As noted above, the larger dimensions of groove **202** permit an amount of tissue to be pushed into groove **204** by tongue **202**.

Adjacent to the distal end of the first leg **102** and immediately inward of hook section **126**, cylindrical bosses **146** and **148** protrude perpendicular to each of the opposed side surfaces **138** and **140**. In the illustrated example of clip **100**, a bridge section **150** couples bosses **146** and **148** together. As evident in Figure 8, bosses **146** and **148** project outwardly beyond convex outer surface **110** of first leg **102**. At the distal end of second or inner leg **104**, cylindrical bosses **152** and **154** protrude perpendicular to each of the opposed side surfaces of inner leg **104** at tip section **128**. Bosses **152** and **154** of second leg **104** extend longitudinally forwardly beyond tip section **128**.

Figure 9 is an enlarged, perspective view of clip **200** compressed around a portion of a vessel. It should be appreciated that clip **200** may be

compressed and latched as described above with reference to clip **100**. In the latched condition, tip section **128** is engaged between concave inner surface **108** and beveled surface **130**, thereby securely clamping a designated vessel or other tissue between concave inner surface **108** and convex inner surface **112**.

Figure 10 is a cross sectional view of clip **200** engaged around a portion of a vessel viewed along line 10—10 in Figure 9. In the area where clip **200** is applied to the vessel, each tongue **202** makes contact with a portion of the vessel and pushes the vessel into opposite groove **204**. The portion of the vessel between tongues **202** conforms around tongues **202** as the vessel is pushed into grooves **204**. Longitudinal movement of the vessel relative to clip **200** is resisted primarily by the portion of the vessel trapped between the medial surfaces of tongues **202**.

Prior art clips similar to clip **100** are described in detail in the commonly assigned U.S. Patent No. 4,834,096 to Oh et al. and 5,062,846 to Oh et al., the disclosures of which are incorporated herein in their entireties. In addition, a particularly suitable clip is the HEM-O-LOK® clip commercially available from the assignee of the present invention. These clips are currently available in sizes designated "M", "ML", "L", and "XL". The clip cartridge of the invention described hereinbelow can be adapted to accommodate any sizes of HEM-O-LOK® clips commercially available.

It will be understood that various details of the invention may be changed without departing from the scope of the invention. Furthermore, the

foregoing description is for the purpose of illustration only, and not for the purpose of limitation—the invention being defined by the claims.